Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products

Real-World Evidence Guidance Webinar Series

April 13, 2023 from 2-3 pm ET

Agenda

Webinar Goal: Provide an overview of recent draft guidance and address questions from the public related to *Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products*.

2 pm Welcome

Susan C. Winckler, RPh, Esq, CEO, Reagan-Udall Foundation for the FDA

2:05 pm Opening Remarks

John Concato, MD, MS, MPH, Associate Director for Real-World Evidence Analytics, Office of Medical Policy, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

2:10 pm Overview of Draft Guidance

Speakers:

- **Motiur Rahman, PhD, MPharm, MS**, Senior Epidemiologist at Real-World Evidence Analytics, Office of Medical Policy, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
- **Pallavi Mishra-Kalyani, PhD,** Supervisory Mathematical Statistician in the Division of Biometrics V, Office of Biostatistics, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

2:40 pm Question and Answer

Moderator: **Susan C. Winckler, RPh, Esq**

Panelists:

- **John Concato, MD, MS, MPH**
- **Motiur Rahman, PhD, MPharm, MS**
- **Pallavi Mishra-Kalyani, PhD**

2:55 pm Closing Remarks

Susan C. Winckler, RPh, Esq

3 pm Adjourn

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